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(54) Systems for endovascular aneurysm treatment

(57) Aneurysms are treated by filling a double-walled filling structure with a curable medium. The structures may be delivered over balloon deployment mechanisms in order to shape and open tubular lumens therethrough. The filling stuctures are preferably used in pairs for providing flow into the iliac arteries when treating abdominal aortic aneurysm.

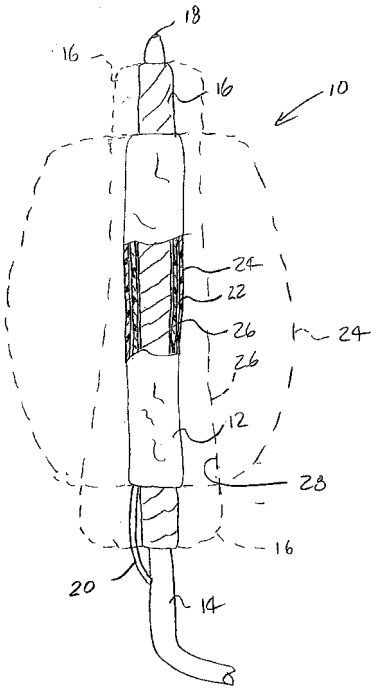

FIG_1

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Description

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention. The present invention relates generally to medical apparatus and methods for treatment. More particularly, the present invention relates to expandable prosthesis and methods for treating abdominal and other aneurysms.

[0002] Aneurysms are enlargements or "bulges" in blood vessels which are often prone to rupture and which therefore present a serious risk to the patient. Aneurysms may occur in any blood vessel but are of particular concern when they occur in the cerebral vasculature or the patient's aorta.

[0003] The present invention is particularly concerned with aneurysms occurring in the aorta, particularly those referred to as aortic aneurysms. Abdominal aortic aneurysms (AAA's) are classified based on their location within the aorta as well as their shape and complexity. Aneurysms which are found below the renal arteries are referred to as infrarenal abdominal aortic aneurysms. Suprarenal abdominal aortic aneurysms occur above the renal arteries, while thoracic aortic aneurysms (TAA's) occur in the ascending, transverse, or descending part of the upper aorta.

[0004] Infrarenal aneurysms are the most common, representing about seventy percent (70%) of all aortic aneurysms. Suprarenal aneurysms are less common, representing about 20% of the aortic aneurysms. Thoracic aortic aneurysms are the least common and often the most difficult to treat. Most or all present endovascular systems are also too large (above 12F) for percutaneous introduction.

[0005] The most common form of aneurysm is "fusiform," where the enlargement extends about the entire aortic circumference. Less commonly, the aneurysms may be characterized by a bulge on one side of the blood vessel attached at a narrow neck. Thoracic aortic aneurysms are often dissecting aneurysms caused by hemorrhagic separation in the aortic wall, usually within the medial layer. The most common treatment for each of these types and forms of aneurysm is open surgical repair. Open surgical repair is quite successful in patients who are otherwise reasonably healthy and free from significant co-morbidities. Such open surgical procedures are problematic, however, since access to the abdominal and thoracic aortas is difficult to obtain and because the aorta must be clamped off, placing significant strain on the patient's heart.

[0006] Over the past decade, endoluminal grafts have come into widespread use for the treatment of aortic aneurysm in patients who cannot undergo open surgical procedures. In general, endoluminal repairs access the aneurysm "endoluminally" through either or both iliac arteries in the groin. The grafts, which typically have been fabric or membrane tubes supported and attached by various stent structures are then implanted, typically requiring several pieces or modules to be assembled in situ. Successful endoluminal procedures have a much shorter recovery period than open surgical procedures.

[0007] Present endoluminal aortic aneurysm repairs, however, suffer from a number of limitations. A significant number of endoluminal repair patients experience leakage at the proximal juncture (attachment point closest to the heart) within two years of the initial repair procedure. While such leaks can often be fixed by further endoluminal procedures, the need to have such follow-up treatments significantly increases cost and is certainly undesirable for the patient. A less common but more serious problem has been graft migration. In instances where the graft migrates or slips from its intended position, open surgical repair is required. This is a particular problem since the patients receiving the endoluminal grafts are those who are not considered good candidates for open surgery. Further shortcomings of the present endoluminal graft systems relate to both deployment and configuration. The multiple component systems require additional time for introducing each piece and even more time for assembling the pieces *in situ*. Such techniques are not only more time consuming, they are also more technically challenging, increasing the risk of failure. Current devices are also unsuitable for treating many geometrically complex aneurysms, particularly infrarenal aneurysms with little space between the renal arteries and the upper end of the aneurysm, referred to as short-neck or no-neck aneurysms. Aneurysms having torturous geometries, are also difficult to treat.

[0008] For these reasons, it would desirable to provide improved methods, systems, and prosthesis for the endoluminal treatment of aortic aneurysms. Such improved methods, systems, and treatments should preferably provide implanted prosthesis which result in minimal or no endoleaks, which resist migration, which are relatively easy to deploy, which have a low introduction profile (preferably below 12F), and which can treat most or all aneurismal configurations, including short-neck and no-neck aneurysms as well as those with highly irregular and asymmetric geometries. At least some of these objectives will be met by the inventions described hereinafter.

[0009] 2. Description of the Background Art. Grafts and endografts having fillable components are described in U.S. Patent Nos. 4,641,653; 5,530,528; 5,665,117; and 5,769,882; U.S. Patent Publications 2004/0016997; and PCT Publications WO 00/51522 and WO 01/66038.

BRIEF SUMMARY OF THE INVENTION

[0010] The present invention provides methods, systems, and prosthesis for the endoluminal treatment of aneurysms, particularly aortic aneurysms including both abdominal aortic aneurysms (AAA's) and thoracic aortic aneurysms (TAA's). The prosthesis comprise double-walled filling structures which are pre-shaped and otherwise adapted to substantially fill the enlarged volume of

an aneurysm, particularly a fusiform aneurysm, leaving a lumen in place for blood flow.

[0011] The double-walled filling structures will thus usually have a generally toroidal structure with an outer wall, an inner wall, a potential space or volume between the outer and inner walls to be filled with a filling medium, and a generally tubular lumen inside of the inner wall which provides the blood flow lumen after the prosthesis has been deployed. The shape of the filling structure will be preferably adapted to conform to the aneurysm being treated. In some instances, the filling structure can be shaped for the aneurismal geometry of a particular patient using imaging and computer-aided design and fabrication techniques. In other instances, a family or collection of filling structures will be developed having different geometries and sizes so that a treating physician may select a specific filling structure to treat a particular patient based on the size and geometry of that patient's aneurysm. In all instances, the outer wall of the filling structure will conform or be conformable to the inner surface of the aneurysm being treated. While the inner wall of the structure will be aligned with lumens of the blood vessels on either side of the prosthesis after the prosthesis has been deployed.

[0012] The filling structures of the prosthesis will usually be formed from a non-compliant material, such as parylene, Dacron, PET, PTFE, a compliant material, such as silicone, polyurethane, latex, or combinations thereof. Usually, it will be preferred to form at least the outer wall partially or entirely from a non-compliant material to enhance conformance of the outer wall to the inner surface of the aneurysm. This is particularly true when the aneurysm has been individually designed and/or sized for the patient being treated.

[0013] The walls of the filling structures may consist of a single layer or may comprise multiple layers which are laminated or otherwise formed together. Different layers may comprise different materials, including both compliant and/or non-compliant materials. The structure walls may also be reinforced in various ways, including braid reinforcement layers, filament reinforcement layers, and the like. In some instances, it would be possible to include self-expanding scaffolds within the filling structures so that the structures could be initially delivered and be allowed to self-expand at the treatment site, thus obviating the need for an expansion delivery catheter as described as the preferred embodiment below.

[0014] Preferred delivery protocols will utilize delivery catheters having a balloon or other expandable support for carrying the filling structure. When using balloons, the balloons will preferably be substantially or entirely compliant, although non-compliant and combination compliant/non-compliant balloons may also find use. The balloon or other mechanical expansion components of the delivery catheter will initially be disposed within the inner tubular lumen of the filling structure, with the filling structure generally being collapsed into a low width or low profile configuration over the expansion element. The delivery catheter may then be introduced intraluminally, typically into the iliac artery and upwardly to the region within the aorta to be treated. The delivery catheter will also include one or more lumens, tubes, or other components or structures for delivering the filling medium in a fluid form to an internal filling cavity of the filling structure. Thus, the delivery catheter can be used to both initially place and locate the filling structure of the prosthesis at the aneurismal site. Once at the aneurismal site, the internal tubular lumen of the structure can be expanded using the balloon or other expandable element on the delivery catheter. The filling structure itself will be filled and expanded by delivering the filling medium via the catheter into the internal volume of the filling structure. Both expansion and filling operations may be performed simultaneously, or can be performed in either order, i.e. the filling structure may be filled first with the delivery catheter balloon being expanded second, or vice versa. The filling structure(s) and/or delivery balloons may have radiopaque markers to facilitate placement and/or pressure sensors for monitoring filling and inflation pressures during deployment.

[0015] In preferred aspects of the present invention, the filling structure will be filled with a fluid (prior to hardening as described herein below) at a pressure which is lower than that of the expansion force provided by the delivery catheter, typically the filling pressure of the expandable balloon. Typically, the filling structure will be filled with filling medium at a pressure from 80 mm of Hg to 1000 mm of Hg, preferably from 200 mm of Hg to 600 mm of Hg, while the delivery balloon is inflated to a pressure in the range from 100 mm of Hg to 5000 mm of Hg, preferably from 400 mm of Hg to 1000 mm of Hg. These pressures are gage pressures, i.e. measured relative to atmospheric pressure.

[0016] As described thus far, in the present invention includes delivery of a single prosthesis and filling structure to an aneurysm. Delivery of a single filling structure will be particularly suitable for aneurysms which are remote from a vessel bifurcation so that both ends of the filling structure are in communication with only a single blood vessel lumen. In the case of aneurysms located adjacent a vessel bifurcation, such as the most common infrarenal abdominal aortic aneurysms, it will often be preferable to utilize two such filling structures introduced in a generally adjacent, parallel fashion within the aneurismal volume. In the specific case of the infrarenal aneurysms, each prosthesis will usually be delivered separately, one through each of the two iliac arteries. After locating the filling structures of the prosthesis within the aneurismal space, they can be filled simultaneously or sequentially to fill and occupy the entire aneurismal volume, leaving a pair of blood flow lumens.

[0017] Suitable filling materials will be fluid initially to permit delivery through the delivery catheter and will be curable or otherwise hardenable so that, once in place, the filling structure can be given a final shape which will remain after the delivery catheter is removed. The fillable

materials will usually be curable polymers which, after curing, will have a fixed shape with a shore hardness typically in the range from 10 durometer to 140 durometer. The polymers may be delivered as liquids, gels, foams, slurries, or the like. In some instances, the polymers may be epoxies or other curable two-part systems. In other instances, the polymer may comprise a single material which when exposed to the vascular environment within the filling structure changes state over time, typically from zero to ten minutes.

[0018] In a preferred aspect of the present invention, after curing, the filling material will have a specific gravity, typically in the range from 0.1 to 5, more typically from 0.8 to 1.2 which is generally the same as blood or thrombus. The filling material may also include bulking and other agents to modify density, viscosity, mechanical characteristics or the like, including microspheres, fibers, powders, gasses, radiopaque materials, drugs, and the like. Exemplary filling materials include polyurethanes, collagen, polyethylene glycols, microspheres, and the like.

[0019] Preferably, the filling structures of the prosthesis will require no additional sealing or anchoring means for holding them in place within the aneurysm. In some instances, however, it may be desirable to employ such additional sealing or anchoring mechanisms, such as stents, scaffolds, hooks, barbs, sealing cuffs, and the like. For sealing cuffs or stents which extend proximately of infrarenal prosthesis, it may be desirable to provide openings or ports to allow the anchoring or sealing devices to extend over the renal ostia while penetrating blood flow into the renal arteries. The sealing or anchoring devices will typically be attached to and/or overlap with the filling structure of the prosthesis and will provide for a smooth transition from the aortic and/or iliac lumens into the tubular lumens provided by the deployed filling structures.

[0020] The filling structures may be modified in a variety of other ways within the scope of the present invention. For example, the external surfaces of the filling structures may be partially or entirely modified to enhance placement within the aneurismal space, typically by promoting tissue ingrowth or mechanically interlocking with the inner surface of the aneurysm. Such surface modifications include surface roughening, surface stippling, surface flocking, fibers disposed over the surface, foam layers disposed over the surface, rings, and the like. It is also possible to provide biologically active substances over all or a portion of the external surface of the filling structure, such as thrombogenic substances, tissue growth promotants, biological adhesives, and the like. It would further be possible to provide synthetic adhesives, such as polyacrylamides, over the surface to enhance adherence.

[0021] In some instances, it will be desirable to modify all or a portion of the internal surface of the filling cavity of the filling structure. Such surface modifications may comprise surface roughening, rings, stipples, flocking, foam layers, fibers, adhesives, and the like. The purpose of such surface modification will usually be to enhance the filling and bonding to the filling material, and to control the minimum wall thickness when the structure is filled particularly after the filling material has been cured. In particular instances, in locations of the filling structure which will be pressed together when the structure is deployed, thus potentially excluding filling material, it will be desirable if the surfaces of the filling structure can adhere directly to each other.

[0022] In view of the above general descriptions of the present invention, the following specific embodiments may be better understood. In a first specific embodiment, methods for treating an aneurysm comprise positioning at least one double-walled filling structure across the aneurysm. By "across" the aneurysms, it is meant generally that the filling structure will extend axially from one anatomical location which has been identified by imaging or otherwise as the beginning of the aneurysm to a space-part location (or locations in the case of bifurcated aneurysm) where it has been established that the aneurysm ends. After positioning, the at least one filling structure is filled with a fluid filling medium so that an out wall of the structure conforms to the inside of the aneurysm and an inner wall of the structure forms a generally tubular lumen to provide for blood flow after the filling structure has been deployed. The tubular lumen will preferably be supported, typically by a balloon or mechanically expansible element, while the filling structure is being filled, after the filling structure has been filled, or during both periods. After the filling structure has been filled, the filling material or medium is hardened while the tubular lumen remains supported. Supporting the tubular lumen during hardening assures that the lumen will have a desired geometry, will properly align with adjacent vascular lumens and that the tubular lumen being formed remains aligned with the native aortic and/or iliac artery lumens after the prosthesis has been fully implanted. Preferably, the support will be provided by a balloon which extends proximally and distally of the filling structure where the balloon may slightly "overexpand" in order to assure the desired smooth transition and conformance of the tubular lumen provided by the filling structure with the native vessel lumens.

[0023] After hardening, the support will be removed, leaving the filling structure in place. In some instances, however, prior to hardening, it will be desirable to confirm proper placement of the filling structure. This can be done using imaging techniques or otherwise testing for patency and continuity. In some instances, it may be desirable to first fill the filling structure with saline or other non-hardenable substance to make sure that the geometry of the filling structure is appropriate for the patient being treated. After testing, the saline may be removed and replaced with the hardenable filler.

[0024] In a second specific embodiment of the present invention, abdominal aortic aneurysms and other bifurcated aneurysms are treated by positioning first and second double-walled filling structures within the aneurismal

volume. The first and second double-walled filling structures are positioned across the aneurysm, as defined above, extending from the aorta beneath the renal arteries to each of the iliac arteries, respectively. The first fluid filling structure is filled with a fluid filling material, the second filling structure is also filled with a fluid material, and the outer walls of each filling structure will conform to the inside surface of the aneurysm as well as to each other, thus providing a pair of tubular lumens for blood flow from the aorta to each of the iliac arteries. Preferably, the tubular lumens of each of the first and second filling structures are supported while they are being filled or after they have been filled. Still further preferably, the tubular lumens will remain supported while the filling material is hardened, thus assuring that the transitions to the tubular lumens to the native vessel lumens remain properly aligned and conformed.

[0025] In a third specific embodiment of the present invention, systems for treating aneurysms comprise at least one double-walled filling structure and at least one delivery catheter having an expandable support positionable within a tubular lumen of the filling structure. The systems will usually further comprise a suitable hardenable or curable fluid filling medium. The particular characteristics of the filling structure and delivery balloon have been described above in connection with the methods of the present invention.

[0026] In a still further specific embodiment of the present invention, a system for treating abdominal aortic aneurysms comprises a first double-walled filling structure and a second double-walled filling structure. The first and second filling structures are adapted to be filled with a hardenable filling medium while they lie adjacent to each other within the aneurysm. The systems further comprise first and second delivery catheters which can be utilized for aligning each of the first and second filling structures properly with the right and left iliacs and the infrarenal aorta as they are being deployed, filled, and hardened.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Fig. 1 illustrates a single prosthesis system comprising a filling structure mounted over a delivery catheter.

[0028] Fig. 2 is a cross-sectional view of the filling structure of Fig. 1 illustrating various surface modifications and a filling valve.

[0029] Figs. 3A-3C illustrate alternative wall structures for the filling structure.

[0030] Fig. 4 illustrates the anatomy of an infrarenal abdominal aortic aneurysm.

[0031] Figs. 5A-5D illustrate use of the prosthesis system of Fig. 1 for treating the infrarenal abdominal aortic aneurysm.

[0032] Fig. 6 illustrates a system in accordance with the principles of the present invention comprising a pair of prosthesis for delivery to an infrarenal abdominal aortic aneurysm, where each prosthesis comprises a filling structure mounted on a delivery catheter.

[0033] Figs. 7A-7F illustrate use of the prosthesis system of Fig. 6 for treating an infrarenal abdominal aortic aneurysm.

DETAILED DESCRIPTION OF THE INVENTION

[0034] A system 10 constructed in accordance with the principles of the present invention for delivering a double-walled filling structure 12 to an aneurysm includes the filling structure and a delivery catheter 14 having an expandable element 16, typically an inflatable balloon, at its distal end. The catheter 14 will comprise a guidewire lumen 18, a balloon inflation lumen (not illustrated) or other structure for expanding other expandable components, and a filling tube 20 for delivering a filling medium or material to an internal space 22 of the double-walled filling structure 12. The internal space 22 is defined between an outer wall 24 and inner wall 26 of the filling structure. Upon inflation with the filling material or medium, the outer wall will expand radially outwardly, as shown in broken line, as will the inner wall 26, also shown in broken line. Expansion of the inner wall 26 defines an internal lumen 28. The expandable balloon or other structure 16 will be expandable to support an inner surface of the lumen 28, as also in broken line in Fig. 1.

[0035] Referring now to Fig. 2, and the various internal and external surfaces may be shaped, coated, treated, or otherwise modified, to provide for a number of particular features in accordance with the principles of the present invention. For example, the outer wall 24 may be shaped to have rings, stipples, or other surface features which are typically formed into the material of the structure at the time of molding, vapor deposition, or other manufacturing process. The outer surface may also be coated with materials 28 which can be adhesives, drugs, active substances, fibers, flocking, foams, or a variety of other materials. In most cases, such surface features or modifications will be intended to enhance sealing or attachment of the outer wall 24 to the inner surface of the aneurysm being treated.

[0036] The inner surface 30 of the filling volume 22 may also be modified by providing features, coatings, surface roughening, or a variety of other modifications. The purpose of such internal features is typically to enhance adherence of the walls to the filling material or medium as the medium is cured or otherwise hardened. In some instances, materials may be coated on all or a portion of the inside surface 30 to induce or catalyze hardening of the filling material as it is being introduced.

[0037] The double-walled filling structure 12 will typically comprise at least one valve 40 to permit the introduction of the filling material or medium into the internal volume 22. As illustrated, the valve 40 may be a simple flap valve. Other more complex ball valves, and other one-way valve structures may be provided. In other instances, two-way valve structures may be provided to

permit both filling and selective emptying of the internal volume 22. In other instances, the filling tube may comprise a needle or other filling structure to pass through the valve 40 to permit both filling and removal of filling medium.

[0038] As illustrated in Fig. 2, the wall structure of the double-walled filling structure may be a single layer, typically molded or otherwise conventionally formed. The wall structures may also be more complex, as illustrated for example, Figs 3A-3C. Fig. 3A shows a multilayered wall comprising layers 42, 43 and 44. It will be appreciated that such multiple layer structure can provide for increased strength, puncture resistance, variations in compliance and/or flexibility, differences in resistance to degradation, and the like. As shown in Fig. 3B, a single wall or multiple wall structure can be reinforced by braid, coils, or other metal or non-polymeric reinforcement layers or structures. As shown in Fig. 3C, the external surface 24 of the wall may be covered with drugs, fibers, protrusions, holes, active agents or other substances for a variety of purposes.

[0039] Referring now to Fig. 4, the anatomy of an infrarenal abdominal aortic aneurysm comprises the thoracic aorta (TA) having renal arteries (RA) at its distal end above the iliac arteries (IA). The abdominal aortic aneurysm (AAA) typically forms between the renal arteries (RA) and the iliac arteries (IA) and may have regions of mural thrombus (T) over portions of its inner surface (S).

[0040] Referring to Figs. 5A-5D, the treatment system 10 of Fig. 1 may be utilized to treat the complex geometry of the transmural abdominal aortic aneurysm (AAA) of Fig. 4 by first positioning the delivery catheter 14 to place the double-walled filling structure 12 (in its unfilled configuration) generally across the aneurysm from the region of the aorta beneath the renal arteries (RA) to a region over the iliac arteries (IA), as best seen Fig. 5A. Usually, the delivery catheter 14 will be introduced over a guidewire (GW) through a puncture in the patient's groin accessing the iliac artery by the Seldinger technique.

[0041] After the double-walled filling structure 12 is properly positioned, a hardenable inflation medium is introduced into the internal space 22 filling of the inner space 22 expands the outer wall 24 of the structure outwardly so that it conforms to the inner surface (S) of the aneurismal space.

[0042] Before, during, or after filling of the double-walled filling structure 12 with inflation medium, as illustrated in Fig. 5B, the balloon 16 or other expansible structure will also be inflated or expanded to open the tubular lumen defined by the interior of the inner wall 26. In a preferred embodiment, the balloon 16 will be generally non-compliant, typically having a maximum diameter of width which is at or slightly larger than the desired tubular lumen diameter or width through the deployed filling structure 12. The filling structure 12, in contrast, will be partially or completely formed from a generally compliant material, thus allowing the non-compliant balloon or other expansible structure 16 to fully open the tubular lumen and conform the ends of the lumens to the aorta and iliac walls, as illustrated in Fig. 5C. A lower or proximal end 50 of the tubular lumen will be flared to a larger diameter so that it can accommodate the openings into both of the iliac arteries (IA) as illustrated. Thus, it will be preferred to utilize a filling structure 12 geometry which has been chosen or fabricated to match the particular patient geometry being treated. It will also be preferable to use a balloon 16 or other expansible structure which will be shaped to preferentially open the lower proximal end 50 of the tubular lumen to a larger diameter than the upper or distal end 52.

[0043] After the filling material has been introduced to the filling structure 12, typically through the filling tube 20, the fluid filling material must be cured or otherwise hardened to provide for the permanent implant having a generally fixed structure which will remain in place in the particular aneurismal geometry. Methods for curing or hardening the filling material will depend on the nature of the filling material. For example, certain polymers may be cured by the application of energy, such as heat energy or ultraviolet light. Other polymers may be cured when exposed to body temperature, oxygen, or other conditions which cause polymerization of the fluid filling material. Still others may be mixed immediately prior to use and simply cure after a fixed time, typically minutes. Often, after the filling material has been hardened, the delivery catheter 12 may be removed and the filling structure left in place as the completed prosthetic implant.

[0044] In other cases, however, it may be desirable to further position certain seals, anchors, stents, or other additional prosthetic components at either the proximal end 52 or distal end 50 of the graft. As illustrated in Fig. 5D, for example, a stent-like structure may be planted in the upper proximal opening 52 of the tubular lumen of the filling structure 12 in order to help anchor the structure, help prevent intrusion of blood into the region between the outer wall 24 and inner surface (S) of the aneurysm, and to generally improve the transition from the aorta into the tubular lumen. The sealing or anchoring structure may simply comprise a stent-like component, preferably having a port or other access route to allow blood flow into the covered renal arteries (if any). Alternatively, the anchor structure could be another inflatable unit, such as the anchor described in co-pending, commonly owned application number 10/668,901 (published as US2004/0116997A1), the full disclosure of which is incorporated herein by reference.

[0045] In a particular and preferred aspect of the present invention, a pair of double-walled filling structures will be used to treat infrarenal abdominal aortic aneurysms, instead of only a single filling structure as illustrated in Figs. 5A-5C. A system comprising such a pair of filling structures is illustrated in Fig. 6 which includes a first filling structure 112 and a second filling structure 212. Each of the filling structures 112 and 212 are mounted on delivery catheters 114 and 214, respectively. The

components of the filling structures 112 and 212 and delivery catheters 114 and 214 are generally the same as those described previously with respect to the single filling structure system 10 of Fig. 1. Corresponding parts of each of the fillings systems 112 and 212 will be given identical numbers with either the 100 base number or 200 base number. A principal difference between the filling structures 112 and 212, on the one hand, and the filling structure 12 of Fig. 1 is that the pair of filling structures will generally have asymmetric configurations which are meant to be positioned adjacent to each other within the aneurismal space and to in combination fill that space, as will be described with specific reference to Fig. 7A-7F below.

[0046] In treating an infrarenal abdominal aortic aneurysm using the pair of filling structures 112 and 212 illustrated in Fig. 6, a pair of guidewires (GW) will first be introduced, one from each of the iliac arteries (IA). As illustrated in Fig. 7A. The first delivery catheter 11.4 will then be positioned over one of the guidewires to position the double-walled filling structure 112 across the aortic aneurysm (AAA), as illustrated in Fig. 7B. The second delivery catheter 214 is then delivered over the other guidewire (GW) to position the second filling structure 212 adjacent to the first structure 112 within the aneurysm (AAA), as illustrated in Fig. 7C. Typically, one of the filling structures and associated balloons will be expanded first, followed by the other of the filling structures and balloon, as illustrated in Fig. 7D where the filling structure 112 and balloon 116 are inflated to fill generally half of the aneurismal volume, as illustrated in Fig. 7D. Filling can generally be carried out as described above with the one filling structure embodiment, except of course that the filling structure 112 will be expanded to occupy only about one-half of the aneurismal volume. After the first filling structure 112 has been filled, the second filling structure 212 may be filled, as illustrated in Fig. 7E. The upper ends of the balloons 116 and 216 will conform the tubular lumens of the filling structures against the walls of the aorta as well as against each other, while the lower ends of the balloons 116 and 216 will conform the tubular lumens into the respective iliac (IA).

[0047] After filling the filling structures 112 and 212 as illustrated in Fig. 7E, the filling materials or medium will be cured or otherwise hardened, and the delivery catheters 114 and 214 removed, respectively. The hardened filling structures will then provide a pair of tubular lumens opening from the aorta beneath the beneath the renal arteries to the right and left iliac arteries, as shown in broken line in Fig. 7. The ability of the filling structures 112 and 212 to conform to the inner surface (S) of the aneurysm, as shown in Fig. 7F, helps assure that the structures will remain immobilized within the aneurysm with little or no migration. Immobilization of the filling structures 112 and 114 may be further enhanced by providing any of the surface features described above in connection with the embodiments of Fig. 2. Optionally, and not illustrated, anchoring or sealing structures could be provided in either of the upper or proximal openings of the tubular lumens into the aorta or from either of the distal or lower openings into the respective iliac arteries.

THE DISCLOSURE OF THIS APPLICATION ALSO INCLUDES THE FOLLOWING NUMBERED CLAUSES:

[0048]

1. A method for treating an aneurysm, said method comprising:

positioning at least one double-walled filling structure across the aneurysm; filling at least one filling structure with a fluid filling medium so that an outer wall conforms to the inside of the aneurysm and an inner wall forms a generally tubular lumen to provide for blood flow:

supporting the tubular lumen while and/or after the filing structure is being filled; hardening the filling medium while the tubular lumen remains supported; and removing support after the filling material has hardened.

2. A method as in clause 1 wherein the tubular lumen support extends upstream and downstream from the double-walled filling structure so that tubular support aligns and conforms each end of the filling structure with the blood vessel.

3. A method as in clause 1, wherein at least an outer wall of the filling structure is formed from a non-compliant material.

4. A method as in clause 3, wherein substantially the entire filling structure is formed from a non-compliant material.

5. A method as in clause 3, wherein the tubular support comprises an inflatable support balloon having a compliant structure.

6. A method as in clause 3, wherein the tubular support comprises a mechanical structure expandable to one or more fixed diameters.

7. A method as in clause 1, wherein the filling structure is filled with fluid filling medium at filling pressure and the inflatable support balloon is inflated at an inflation pressure which is great than the filling pressure.

8. A method as in clause 7, wherein the filling pressure is in the range from 100 mm Hg to 1000 mm Hg and the inflation pressure is in the range from 200 mm Hg to 5000 mm Hg.

9. A method as in clause 1, further comprising positioning an anchor or sealing element of at least one opening from the tubular lumen of the filing structure to a lumen of the blood vessel.

10. A method as in clause 9, further comprising positioning an anchor or sealing element at each opening.

11. A method as in clause 1, wherein the filling material comprises a flowable polymer which is curable in situ.

12. A method as in clause 11, wherein the polymer comprises a polyurethane, a polyethylene glycol, a collagen.

13. A method as in clause 11, wherein the filling material has a density in the range form 0.1 gm/cc to 5 gm/cc when hardened.

14. A method as in clause 11, wherein the filling material comprises a two-part curable material which hardened after mixing.

15. A method for treating an abdominal aortic aneurysm between the iliacs and the renal arteries, said method comprising:

positioning a first double-walled filling structure from one iliac, across the aneurysm,
and into the aorta beneath the renal arteries;
positioning a second double-walled filling structure from the other iliac, across the aneurysm, and into the aorta beneath the renal arteries and adjacent to the first double-walled filling structure;
filing the first filling structure with a fluid filling material so that an outer wall conforms to an inside surface of the aneurysm and an inner wall forms a generally tubular lumen from the first iliac to the aorta beneath the renal arteries;
filing the second filling structure with a fluid filling material so that an outer wall conforms to an inside surface of the aneurysm and an inner wall forms a generally tubular lumen from the second iliac to the aorta beneath the renal arteries;
hardening the filling material in the first filling structure; and
hardening the filling material in the second filling structure.

16. A method as in clause 15, further comprising;
supporting the tubular lumen of the first filling structure while an/or after the first filling structure is being filled; and
supporting the tubular lumen of the second filling structure while and/or after the second filling structure is being filled.

17. A method as in clause 16, further comprising:

removing support from the tubular lumen of the first filling structure after the filling material has hardened; and
removing support from the tubular lumen of the second filling structure after the filing material has hardened.

18. A method as in clause 15, wherein the tubular lumen support extends upstream and downstream from each double-walled filling structure so that tubular support aligns and conforms each end of the filling structure with the iliac and aorta.

19. A method as in clause 15, wherein at least an outer wall of the filling structure is formed from a non-compliant material.

20. A method as in clause 19, wherein substantially the entire filling structure is formed from a non-compliant material.

21. A method as in clause 15, wherein the tubular support comprises an inflatable balloon having a compliant structure.

22. A method as in clause 15, wherein the tubular support comprises a mechanical structure expandable to one or more fixed diameters.

23. A method as in clause 15, wherein each filling structure is filled with fluid filling medium at filling pressure and each inflatable support balloon is inflated at an inflation pressure which is great than the filling pressure.

24. A method as in clause 23, wherein the filling pressure is in the range from 100 mm Hg to 1000 mm Hg and the inflation pressure is in the range from 200 mm Hg to 5000 mm Hg.

25. A method as in clause 15, further comprising positioning an anchor or sealing element of at least one opening from the tubular lumen of at least one of the filling structures to a lumen of the iliac or aorta.

26. A method as in clause 25, further comprising positioning an anchor or sealing element at each opening.

27. A method as in clause 15, wherein the filling material comprises a flowable polymer which is curable in situ.

28. A method as in clause 27, wherein the polymer

comprises a polyurethane, a polyethylene glycol, a collagen.

29. A method as in clause 27, wherein the filling material has a specific gravity in the range from 0.1 to 5 when hardened.

30. A method as in clause 27, wherein the filling material comprises a two-part curable material which hardens after mixing.

31. A system as in clause 27, further comprising a filling material including a flowable polymer which is curable in situ.

32. A system as in clause 27, wherein the polymer comprises a polyurethane, a polyethylene glycol, a collagen.

33. A system for treating an aneurysm, said system comprising:

at least one double- walled filling structure having an outer wall and an inner wall, wherein the filling structure is adapted to be filled with a hardenable fluid filling medium so that the outer wall conforms to the inside surface of the aneurysm and the inner surface forms a generally tubular lumen to provide blood flow; and
a delivery catheter having an expandable tubular support which can be positioned within the tubular lumen to carry the double-walled filling structure.

34. A system as in clause 33, wherein the expandable tubular support extends upstream and downstream from the double-walled filling structure so that tubular support aligns and conforms each end of the filling structure with the blood vessel.

35. A system as in clause 33, wherein at least an outer wall of the filling structure is formed from a compliant material.

36. A system as in clause 33, wherein substantially the entire filling structure is formed from a compliant material.

37. A system as in clause 33, wherein the tubular support comprises an inflatable support balloon having a non-compliant structure.

38. A system as in clause 37, wherein the tubular support comprises a mechanical structure expandable to one or more fixed diameters.

39. A system as in clause 33, wherein at least a portion of an exterior surface of the filling structure is modified to enhance sealing or tissue ingrowth.

40. A system as in clause 39, wherein the surface modification comprises surface roughening, an foam layer, fibers, flocking, stipples, or drug coating.

41. A system as in clause 33, wherein at least a portion of an interior surface of the filing structure is modified to enhance hardening of the structure.

42. A system as in clause 41, wherein the surface modification comprises surface roughening, rings, stipples, flocking, a foam layer, or fibers.

43. A system as for treating an abdominal aortic aneurysm between the iliacs and the renal arteries, said system comprising:

a first double-walled filing structure having an outer wall and an inner wall, wherein
the first filling structure is adapted to be filled and expanded with a hardenable fluid filling medium so that the outer wall conforms to an inside surface of the aneurysm and the inner surface forms a generally tubular lumen to provide blood flow; and
a second double- walled filling structure having an outer wall and an inner wall, wherein the second filling structure is adapted to be filled and expanded with a hardenable fluid filling medium so that the outer wall conforms to another inside surface of he aneurysm and the inner surface forms a generally tubular lumen to provide blood flow, and wherein the first and second double-walled filling structures will together substantially fill the entire aneurysm when expanded therein.

44. A system as in clause 43, wherein further comprising;
a first delivery catheter having an expandable support which can be positioned within the tubular lumen of the first double- walled filling structure; and
a second delivery catheter having an expandable support which can be positioned within the tubular lumen of the second double-walled filling structure.

45. A system as in clause 44, wherein the expandable support on each delivery catheter extends upstream and downstream from the double-walled filling structure so that tubular support aligns and conforms each end of the filling structure with the iliac and aorta.

46. A system as in clause 43, wherein at least an outer wall of each filling structure is formed from a compliant material.

47. A system as in clause 43, wherein substantially the entire filling structure is formed from a non-compliant material.

48. A system as in clause 43, wherein the expandable support comprises an inflatable support balloon having a compliant structure.

49. A method as in clause 43, wherein the expandable support on each delivery catheter comprises a mechanical structure expandable to one or more fixed diameter.

50. A system as in clause 43, wherein at least a portion of an exterior surface is modified to enhance sealing or tissue ingrowth.

51. A system as in clause 50, wherein the surface modification comprises roughening, a foam layer, fibers, or drug coating.

52. A system as in clause 43, further comprising a filling material including a flowable polymer which is curable in situ.

53. A system as in clause 43, wherein the polymer comprises a polyurethane, a polyethylene glycol, a collagen.

54. A system as in clause 52, wherein the filling material has a specific gravity in the range from 0.1 to 5 when hardened.

55. A system as in clause 52, wherein the filling material comprises a two-part curable material which hardens after mixing.

Claims

1. A system for treating an aneurysm, said system comprising:

at least one double-walled filling structure having an outer wall and an inner wall, wherein the filling structure is adapted to be filled with a fluid filling medium so that the outer wall conforms to the inside surface of the aneurysm and the inner surface forms a generally tubular lumen to provide blood flow;
a first delivery catheter having a first expandable tubular support positionable within the tubular lumen to carry the double-walled filling structure;
a second double-walled filling structure having an outer wall and an inner wall, wherein the second filling structure is adapted to be filled and expanded with a fluid filling medium so that the outer wall conforms to another inside surface of the aneurysm and the inner surface forms a generally tubular lumen to provide blood flow, the second double-walled filling structure being positionable adjacent the first double-walled filling structure within the aneurysmal space; and
a second delivery catheter having a second expandable tubular support positionable within the tubular lumen to carry the second double-walled filling structure.

2. The system of claim 1, wherein the first and second double walled-filling structure extend across substantially the entire aneurysm when expanded.

3. The system of claim 1, wherein the first and second double walled-filling structure are expandable and conformable so as that, in combination, the first and second double-walled filling structure substantially fill the entire aneurysmal space.

4. A system as in claim 1, wherein the expandable tubular support of at least one delivery catheter extends upstream and downstream from respective double-walled filling structure so that tubular support aligns and conforms each end of the filling structure with the blood vessel.

5. A system as in any one of the preceding claims, wherein at least an outer wall of at least one filling structure is formed from a compliant material.

6. A system as in claim 4, wherein substantially the entire filling structure is formed from a compliant material.

7. A system as in any one of the preceding claims, wherein the tubular support of at least one delivery catheter comprises an inflatable support balloon having a non-compliant structure.

8. A system as in claim 6, wherein the tubular support comprises a mechanical structure expandable to one or more fixed diameters.

9. A system as in any one of the preceding claims, wherein at least a portion of an exterior surface of at least one filling structure is modified to enhance sealing or tissue ingrowth.

10. A system as in any one of the preceding claims, wherein at least a portion of an interior surface of at least one filing structure is modified to enhance hardening of the structure.

11. A system as in claim 9 or 10, wherein the surface modification comprises surface roughening, rings, an foam layer, fibers, flocking, stipples, or drug coating.

12. A system as in any one of the preceding claims, wherein the expandable support on each delivery catheter extends upstream and downstream from the respective double-walled filling structure so that the tubular support is configured to align and conform each end of the respective filling structure with the iliac and aorta.

13. A system as in any one of the preceding claims, wherein the fluid filling medium comprises a flowable polymer which is curable *in situ.*

14. A system as in claim 13, wherein the polymer comprises a polyurethane, a polyethylene glycol, a collagen.

15. A system as in claim 13 or 14, wherein the filling material has a specific gravity in the range from 0.1 to 5 when hardened.

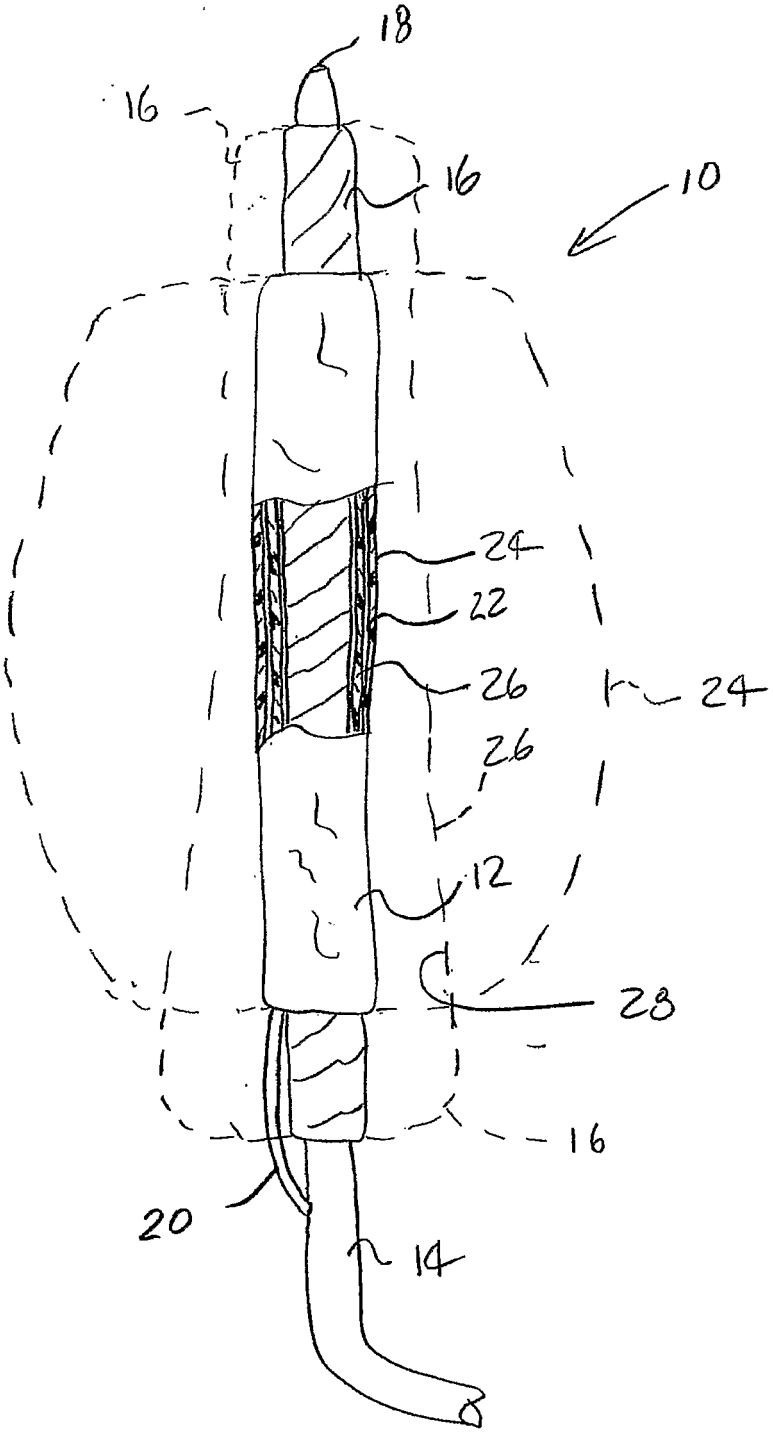

FIG. 1

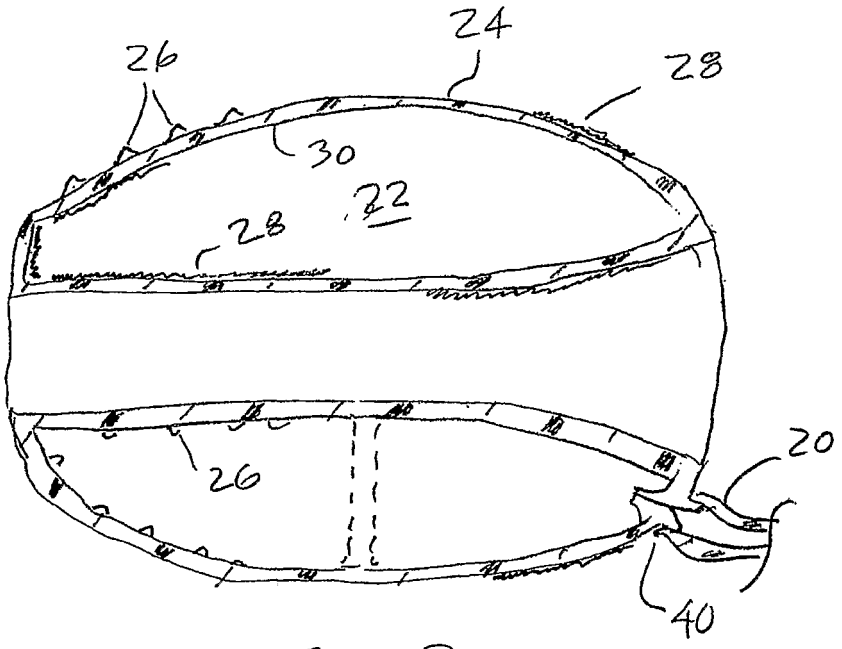

FIG-2

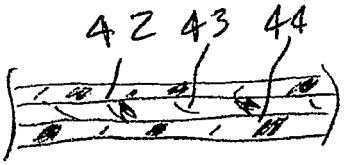

FIG-3A

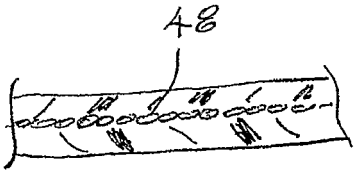

FIG-3B

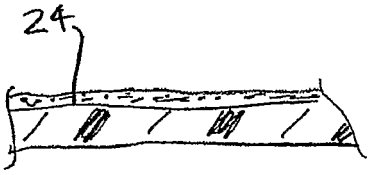

FIG-3C

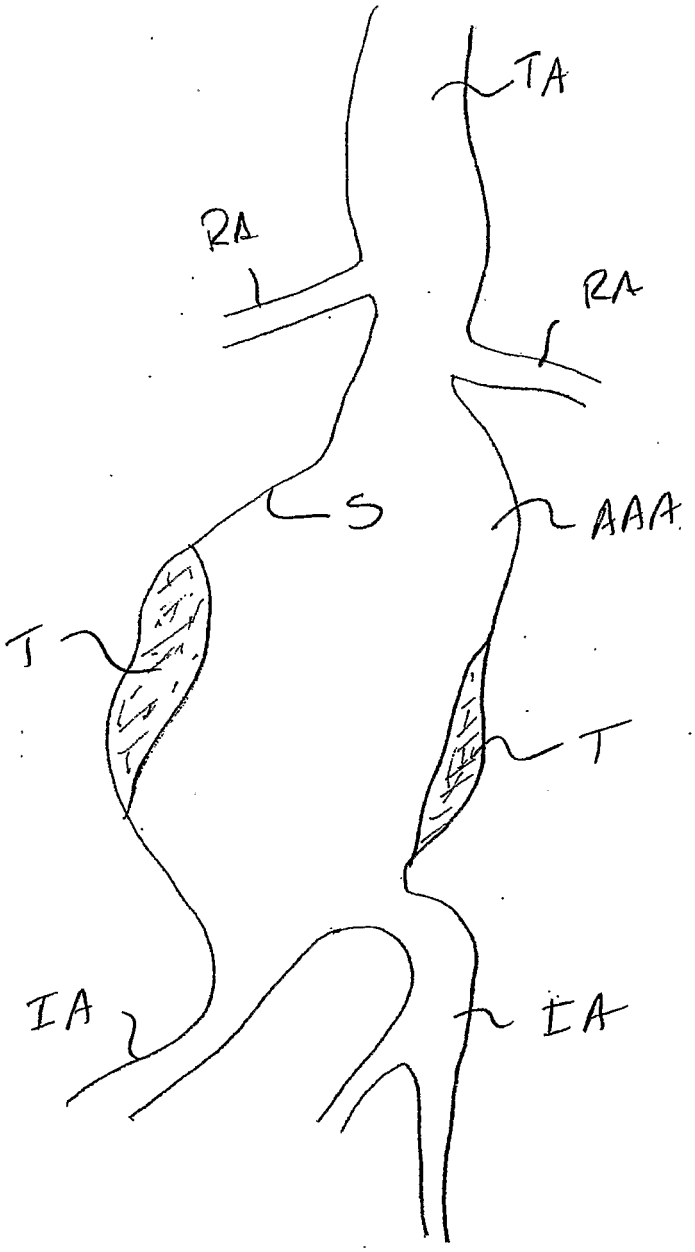

FIG - 4

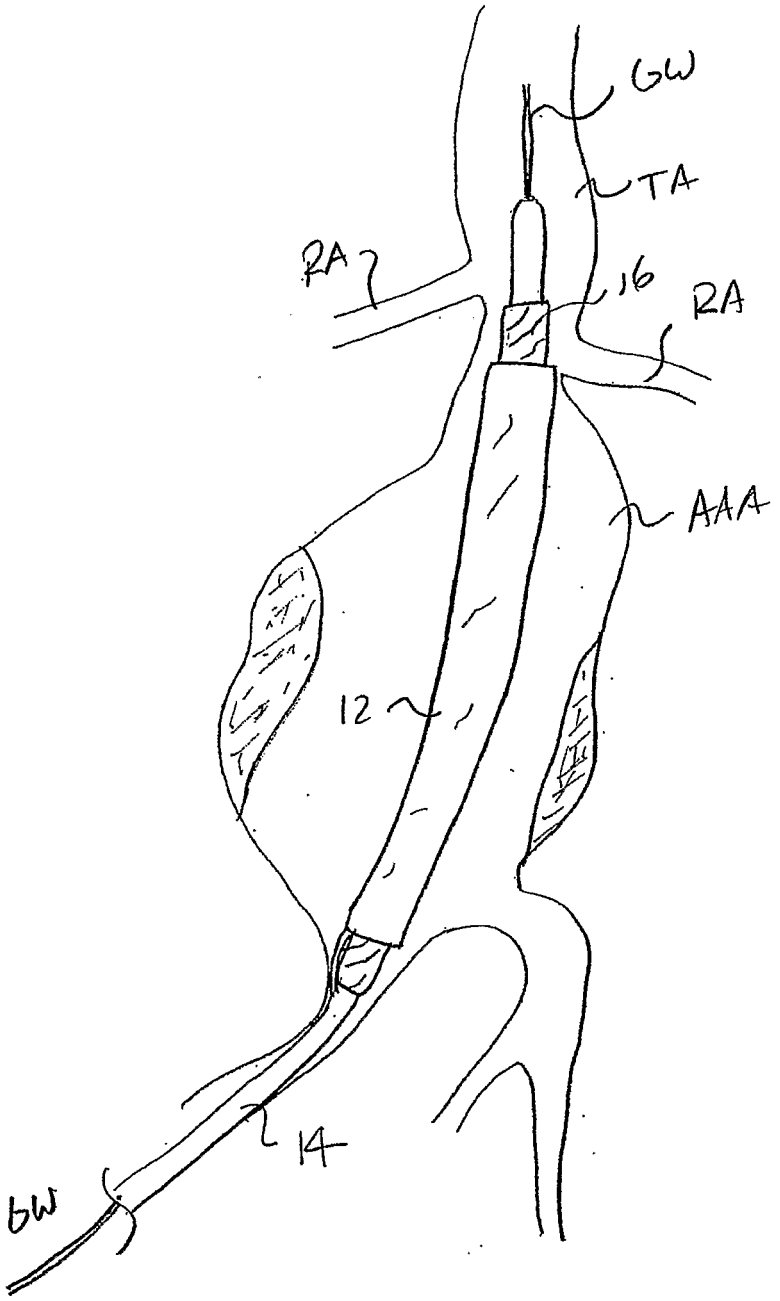

FIG- 5A

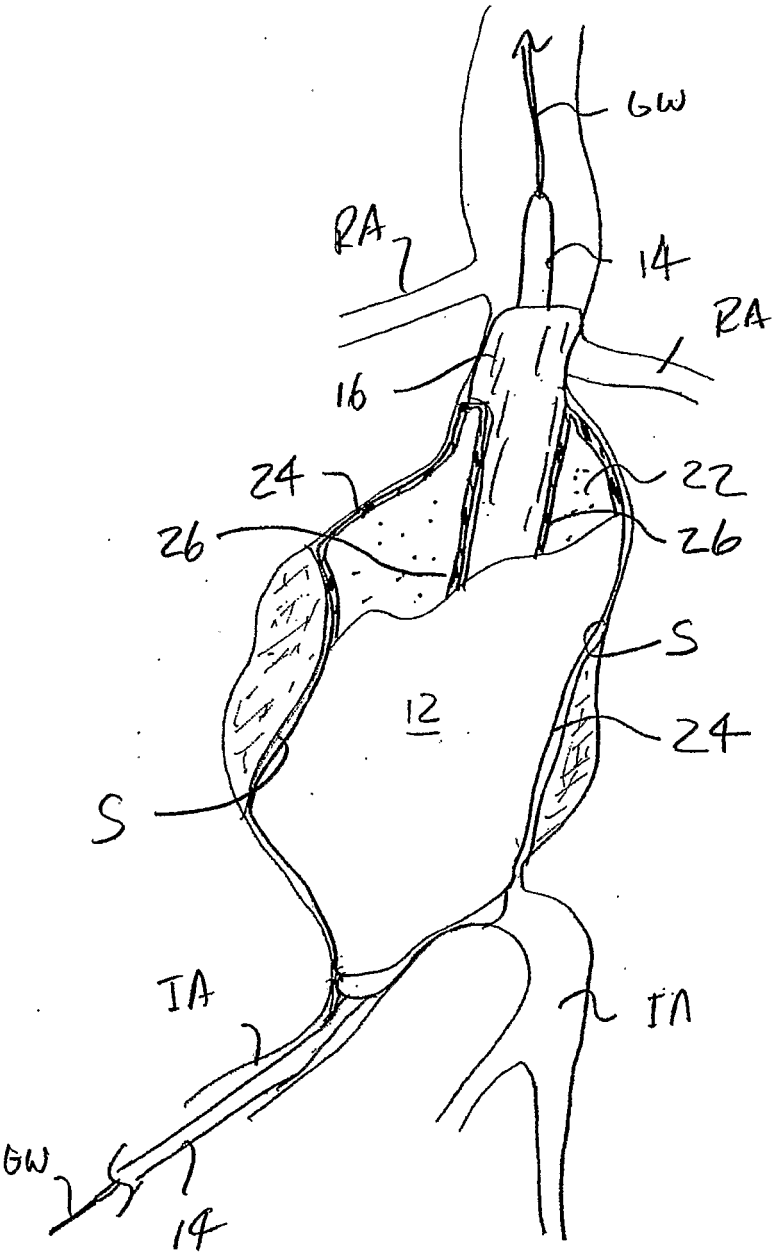

FIG-5B

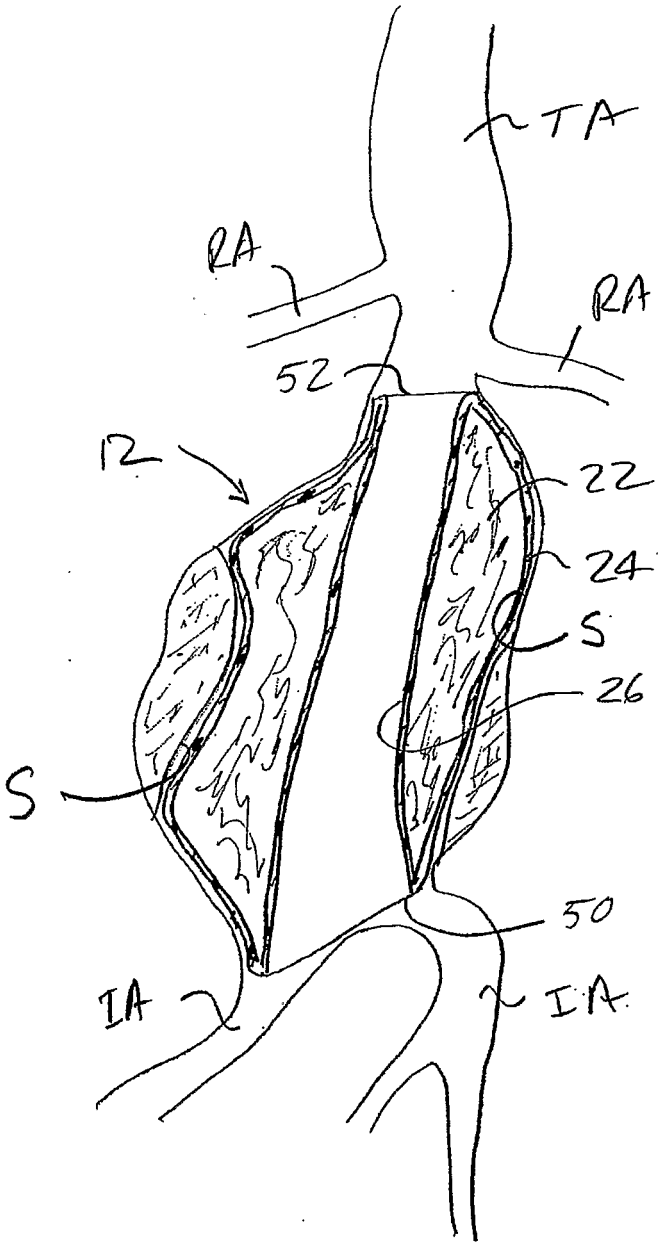

FIG-5C

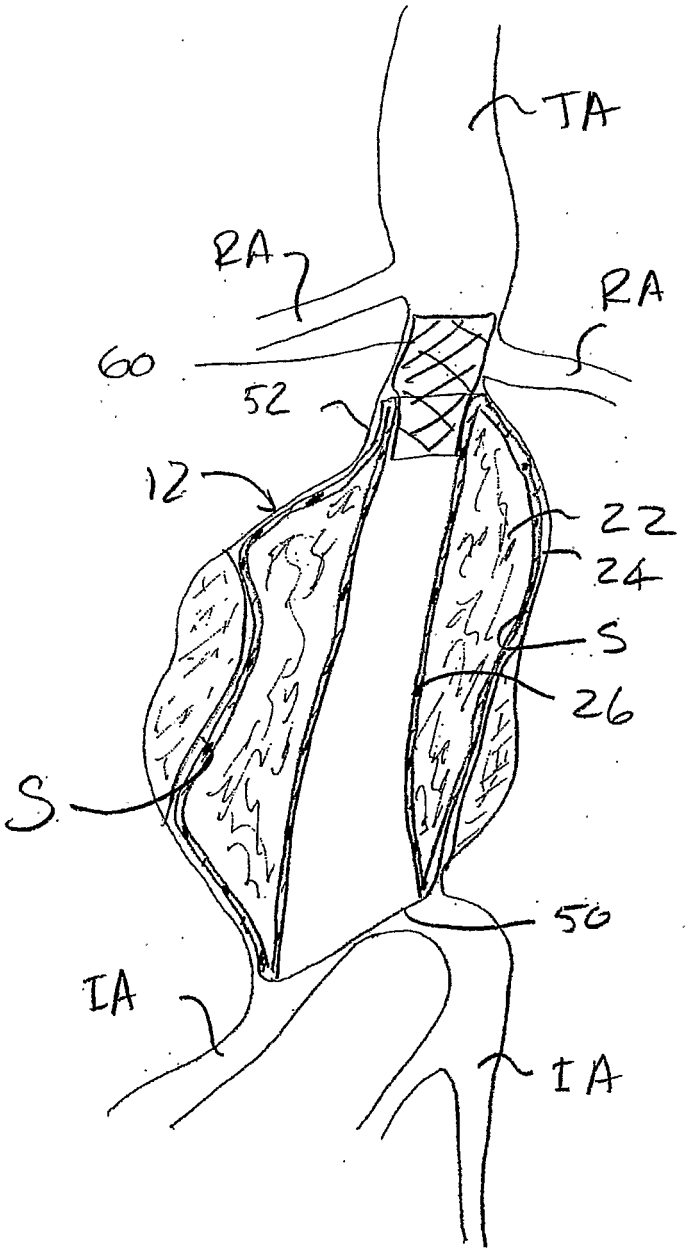

FIG-5D

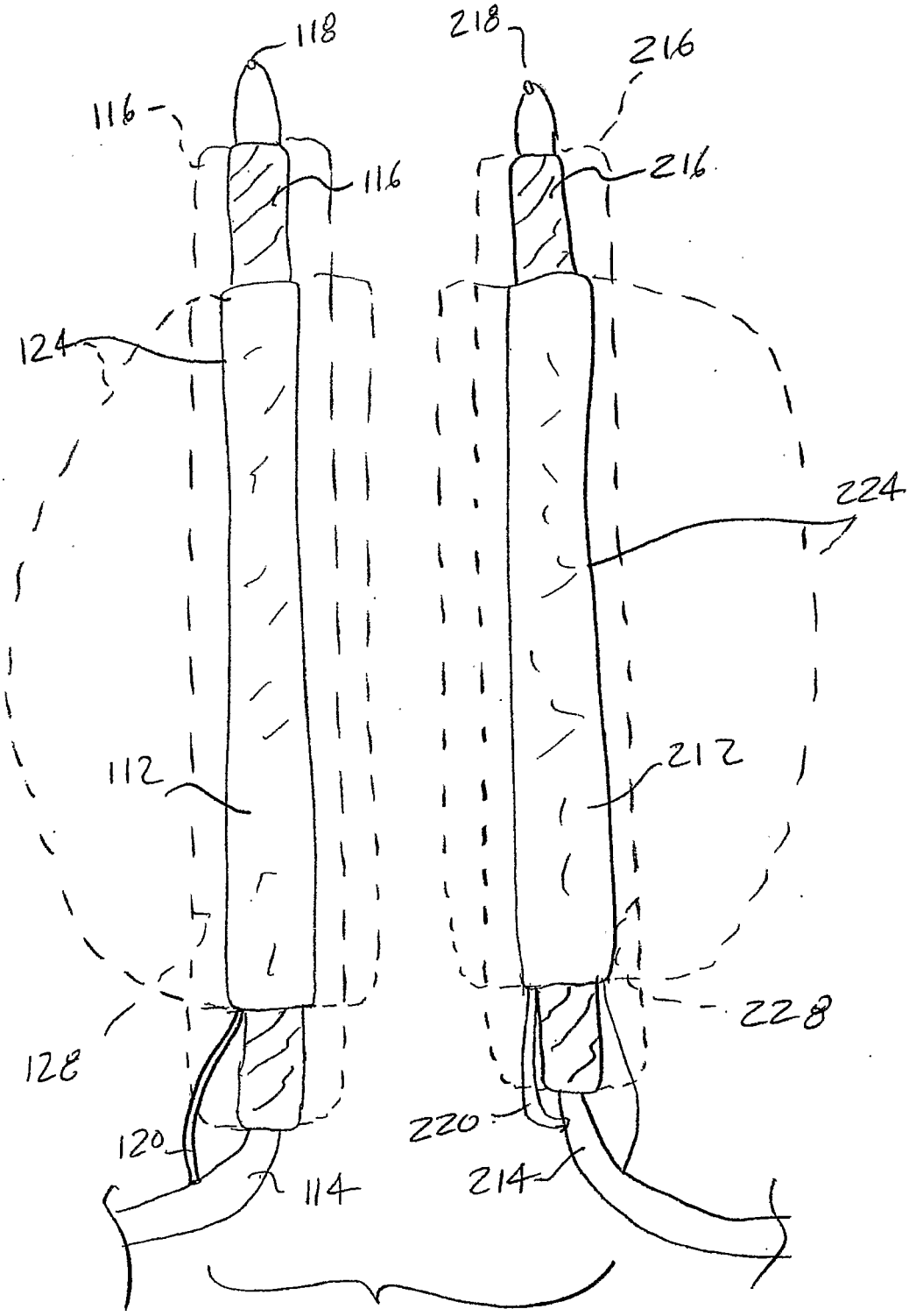

FIG_6

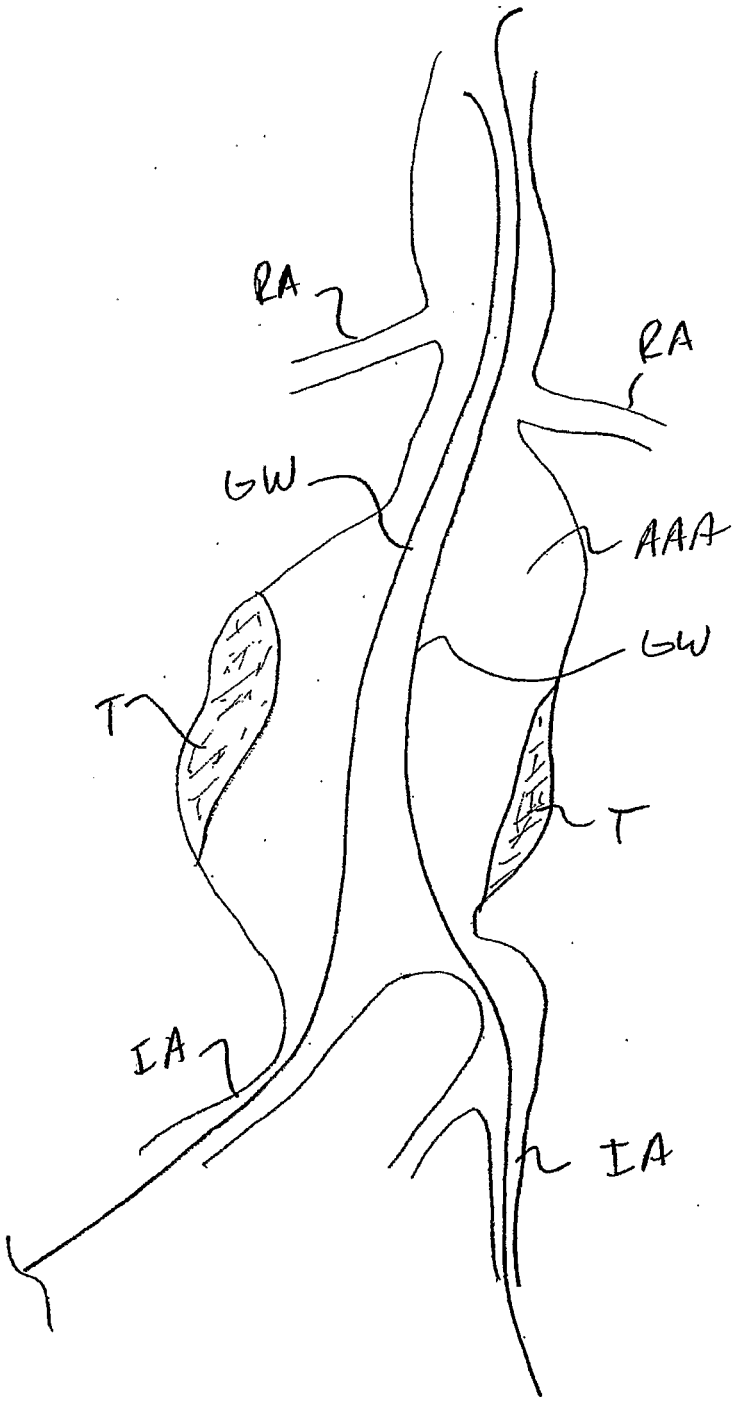

FIG_7A

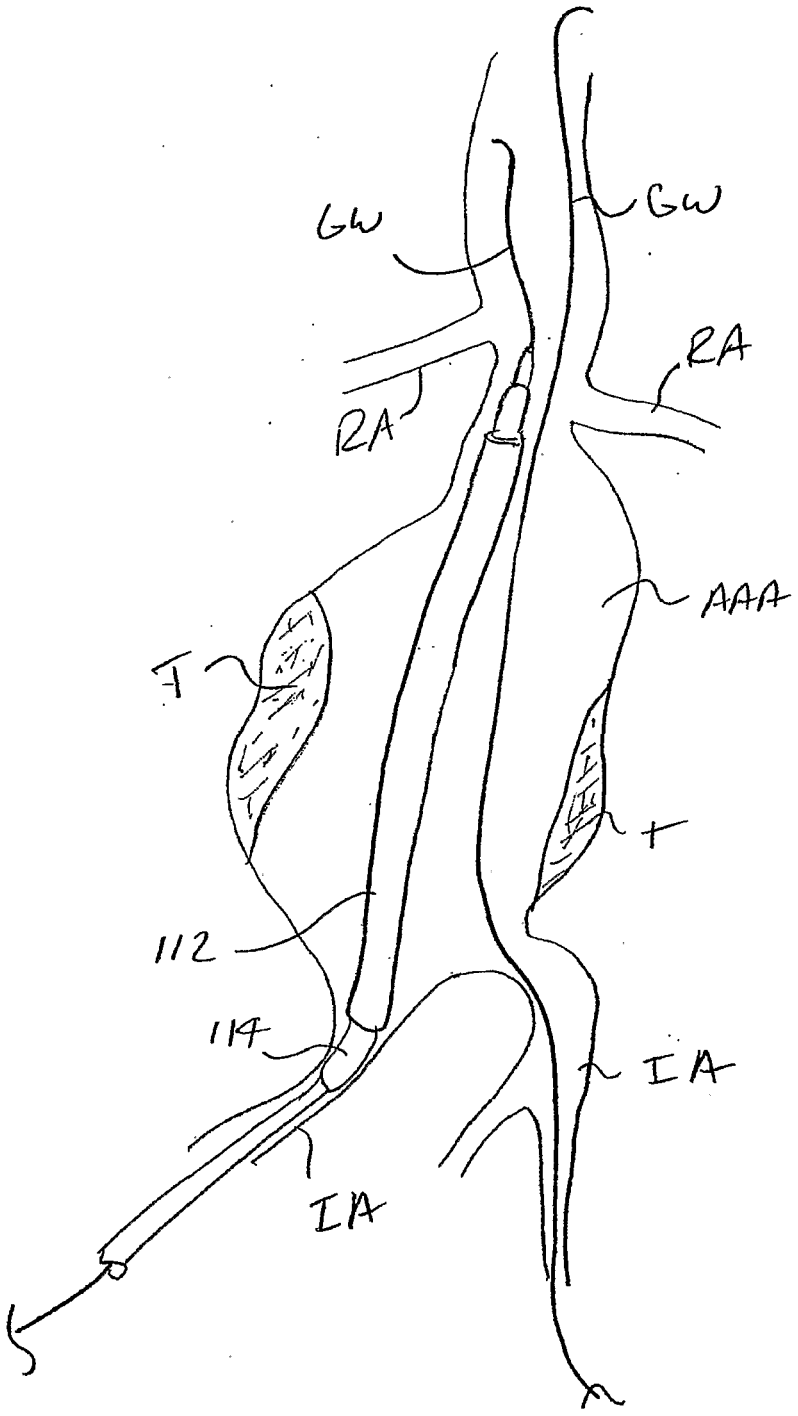

FIG-7B

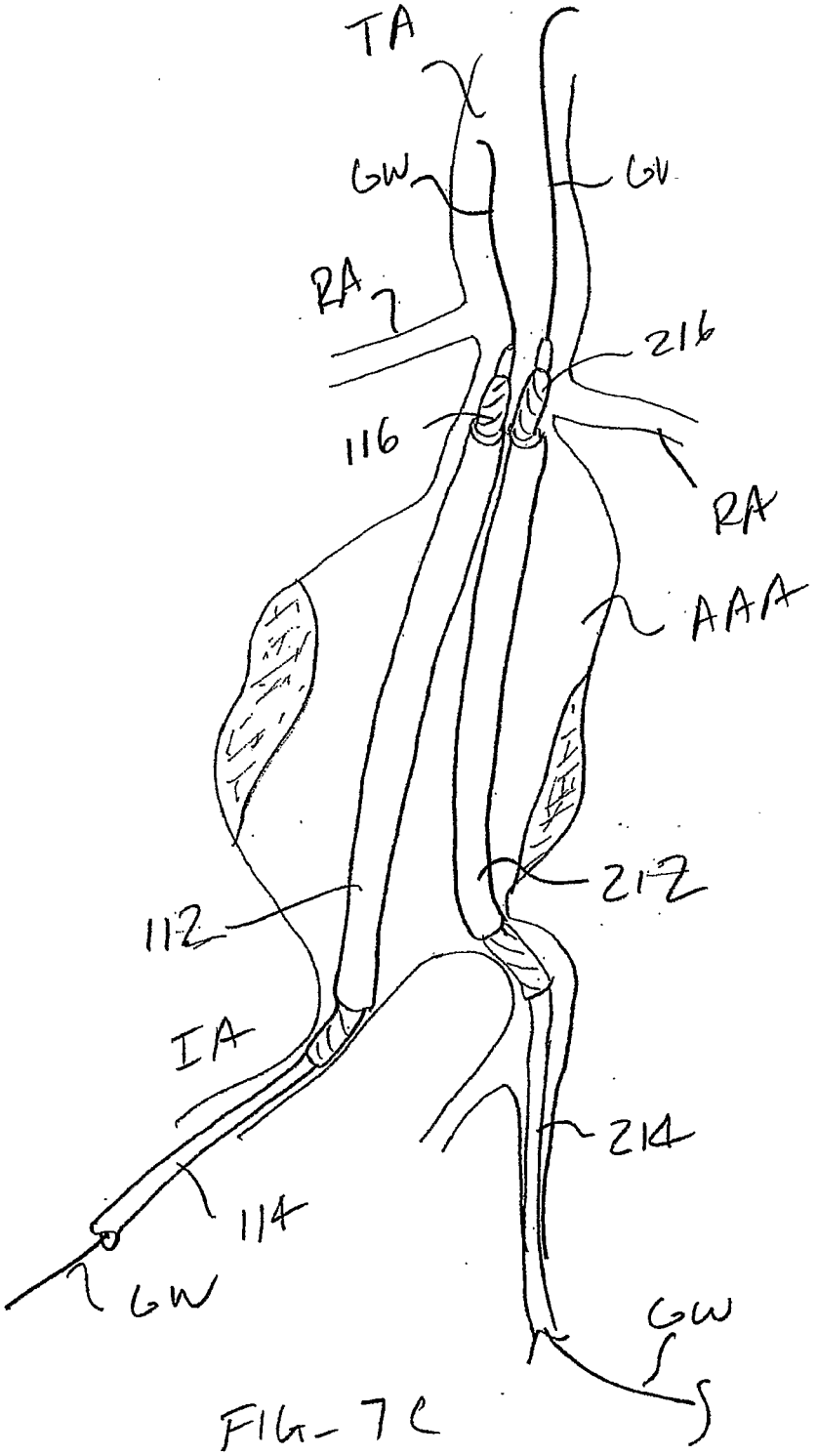

FIG-7C

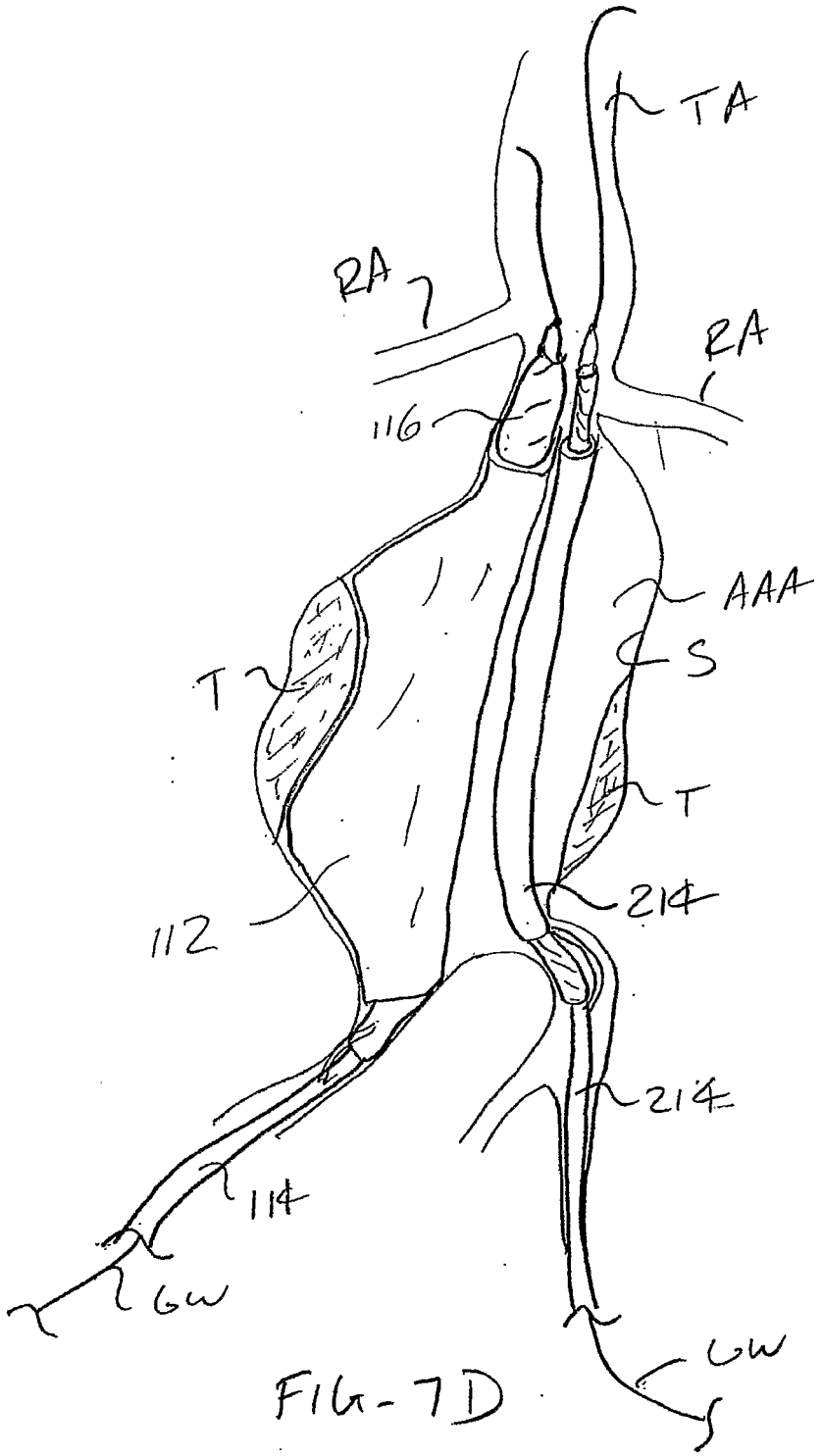

FIG-7D

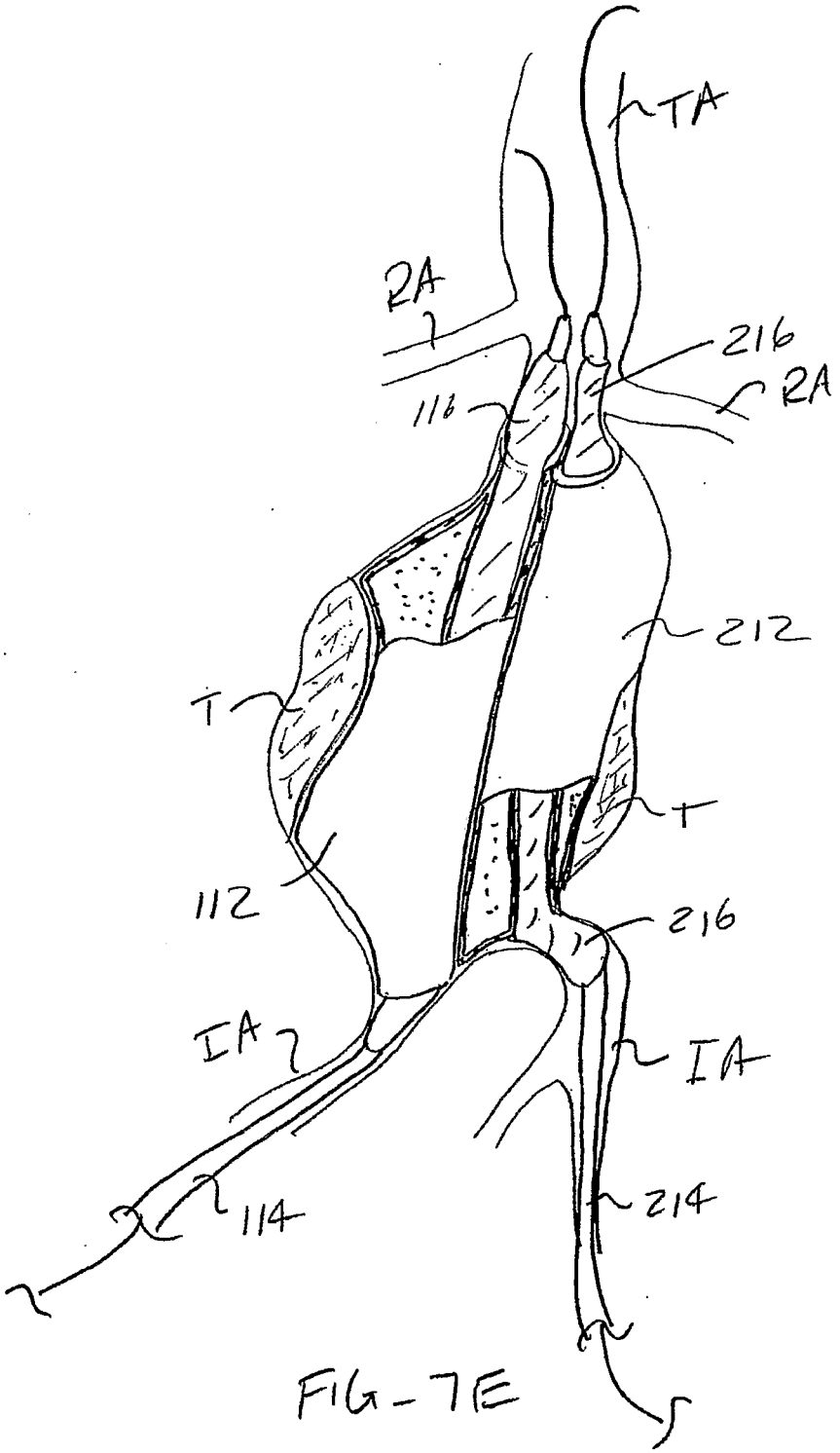

FIG-7E

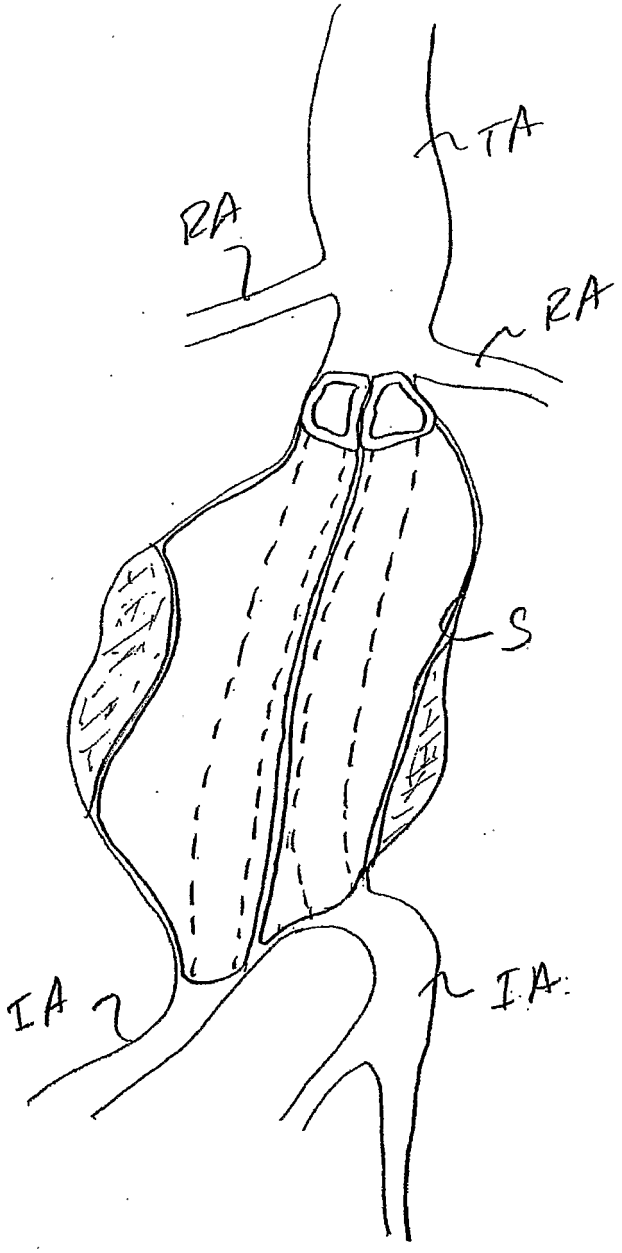

FIG-7F

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EUROPEAN SEARCH REPORT

Application Number
EP 11 18 0827

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2001/027338 A1 (GREENBERG ROY K [US]) 4 October 2001 (2001-10-04)	1	INV. A61F2/06
Y	* paragraphs [0032] - [0033], [0036], [0046], [0048], [0051]; figure 6 *	2-15	
X	US 5 665 117 A (RHODES VALENTINE J [US]) 9 September 1997 (1997-09-09)	1	
Y	* figures 5,9-14 * * column 5, lines 13-32 * * column 8, lines 28-42 * * column 8, line 63 - column 9, line 3 * * column 9, lines 54-65 * * column 10, lines 35-56 * * column 11, lines 7-36 *	2-15	
X	US 2003/120331 A1 (CHOBOTOV MICHAEL V [US] ET AL) 26 June 2003 (2003-06-26)	1	
Y	* paragraphs [0057], [0059], [0060], [0062], [0064], [0065], [0085], [0118], [0135] - [0142], [0149]; figure 2 *	2-15	
			TECHNICAL FIELDS SEARCHED (IPC)
X	WO 03/037222 A2 (COOK INC [US]; COOK WILLIAM A AUSTRALIA [AU]) 8 May 2003 (2003-05-08)	1	A61F
Y	* page 2, lines 9-10 * * page 3, lines 3-6 * * page 8, last line - page 9, line 7 * * figures 1,2,14,15 *	2-15	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	20 January 2012	Serra i Verdaguer, J

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20-01-2012

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2001027338 A1	04-10-2001	AT 255860 T	15-12-2003
		AU 769900 B2	05-02-2004
		AU 4539401 A	17-09-2001
		CA 2397980 A1	13-09-2001
		DE 60101455 D1	22-01-2004
		DE 60101455 T2	23-09-2004
		DK 1259192 T3	29-03-2004
		EP 1259192 A2	27-11-2002
		ES 2211791 T3	16-07-2004
		JP 2003525692 A	02-09-2003
		PT 1259192 E	30-04-2004
		US 2001027338 A1	04-10-2001
		WO 0166038 A2	13-09-2001
US 5665117 A	09-09-1997	AU 1023897 A	19-06-1997
		US 5665117 A	09-09-1997
		WO 9719653 A1	05-06-1997
US 2003120331 A1	26-06-2003	EP 2277474 A2	26-01-2011
		US 2003120331 A1	26-06-2003
		US 2003120338 A1	26-06-2003
		US 2006178732 A1	10-08-2006
		US 2009264984 A1	22-10-2009
		US 2010016942 A1	21-01-2010
		US 2012016457 A1	19-01-2012
WO 03037222 A2	08-05-2003	AT 437615 T	15-08-2009
		CA 2459742 A1	08-05-2003
		EP 1453437 A2	08-09-2004
		JP 4222481 B2	12-02-2009
		JP 2005507707 A	24-03-2005
		US 2003093145 A1	15-05-2003
		WO 03037222 A2	08-05-2003

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Patent documents cited in the description

- US 4641653 A **[0009]**
- US 5530528 A **[0009]**
- US 5665117 A **[0009]**
- US 5769882 A **[0009]**
- US 20040016997 A **[0009]**
- WO 0051522 A **[0009]**
- WO 0166038 A **[0009]**
- US 10668901 B **[0044]**
- US 20040116997 A1 **[0044]**